

REMARKS

A. REQUEST FOR RECONSIDERATION

Applicant has carefully considered the matters raised by the Examiner in the outstanding Office Action dated February 3, 2009, but remains of the opinion that patentable subject matter is present. Applicant respectfully requests reconsideration of the Examiner's position based on the amendments to the claims and the following remarks.

B. THE INVENTION

As defined by the claims presented herein, the invention is directed to a method for suppressing bacterial growth in a prestorage-leuko-reduced platelet concentrate. One of the novel aspects of the invention is that the method allows for the prestorage-leuko-reduced platelet concentrate to be stored for about 7 to 8 days. Prior art methods did not allow for such extended storage periods. Therefore, the claimed invention distinguishes over the prior art.

C. STATUS OF THE CLAIMS AND AMENDMENTS

Claims 57-61 are pending in this application.

Claim 57 has been amended herein to recite that the prestorage-leuko-reduced platelet concentrate can be stored for about 7 to 8 days. Support for this amendment can be found, for example, on page 31, line 4-page 32, line 18.

No new matter has been added herein.

D. PRIOR ART REJECTION

The Examiner rejected the claimed subject matter as unpatentable over Sweeney et al. in combination with US 5,747,536 (the '536 patent) and Ogawa et al. and Tegos et al.

In a previous Office Action, dated June 13, 2008, the Examiner cited the combination of Sweeney, the '536 patent, Ogawa and Tegos to teach a method substantially as claimed. Applicant responded to this rejection made by the Examiner on November 13, 2008 by arguing test data provided in the present application which showed that employing the claimed method of the present invention yielded unexpected results with respect to storage duration and the amount of time bacterial growth is suppressed.

In the current Office Action, the Examiner indicated that the test data provided in the present application and argued in Applicant's response of November 13, 2008 was not commensurate in scope with the claimed invention. The Examiner also stated on page 7 of the Office Action, that "the applicant does not limit the claims to the unexpected results". In response to the Examiner's position, Applicant has amended claim 57 to recite that the prestorage-leuko-reduced platelet concentrate can be stored for about 7 to 8 days. It is respectfully submitted that the claims reflect the unexpected results. Accordingly, the test data demonstrating the unexpected results achieved by the claimed method is commensurate in scope with the claims.

Applicants note that there is a significant improvement in the duration of storage provided by the claimed method. Specifically, it has been found that the claimed method for suppressing bacterial growth in a prestorage-leuko-reduced platelet concentrate allows for about 7 to 8 days of storage of the prestorage-leuko-reduced platelet concentrate. Sweeney, on the other hand, teaches that "the current shelf life of the platelets is 5 days" (emphasis added; page 1313). The state of the art at the time Sweeney was published was such that platelet concentrates were stored for only 5 days because of storage-related deterioration and rapid bacterial growth (page 1313). The '536 patent has no disclosure anywhere of a method for reducing bacterial growth in a prestorage-leuko-reduced platelet concentrate, let alone the duration of storage for such platelet concentrates. With respect to Ogawa and Tegos, these references only showed storage duration of 72 hours (Ogawa, page 104, col. 2; Tegos, page 204, Table 1). Therefore, none of the references cited by the Examiner teach storage of a platelet concentrate for longer than 5 days. Clearly 7 to 8 days is different from, and significantly longer than the no more than 5 days taught in the prior art references cited by the Examiner. Thus, even if one of skill in the art were to combine the references cited by the Examiner, they would not arrive at the claimed method.

Moreover, a platelet concentrate that can be stored up to about 7 to 8 days makes a huge impact on the national and worldwide blood supply. As discussed on page 2 of the present application, for platelets, the current storage period is only 5 days. This is due to decrease in stability of platelets during storage and microbial contamination. A platelet concentrate that is safe for use after a longer storage period improves the confidence in the safety of that platelet supply, and at the same time positively affects the growing need for a larger blood supply in

emergency situations (i.e. terrorist attacks, hurricanes, earthquakes, etc.). Since the prior art references teach a storage duration of no longer than 5 days, they do not teach the claimed method of the present invention.

Since none of the references cited by the Examiner teach storage duration greater than 5 days, the references taken alone or in combination would not lead one of skill in the art to the claimed method. It is respectfully submitted that the claimed method is patentable over the Examiner's rejection.

E. CONCLUSION

In view of the foregoing and the enclosed, it is respectfully submitted that the Application is in condition for allowance and such action is respectfully requested.

F. FEES

This response is being filed within the shortened period for response, thus, no fees are believed due. If it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

Respectfully submitted,

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